PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P209796	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/NL2005/000161	International filing date *(day/month/year)* 04.03.2005	Priority date *(day/month/year)* 04.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A21D8/04 A23L1/00 A23P1/04 A23L1/22 A23P1/02 C12N9/98 C12N11/04		
Applicant CSM NEDERLAND B.V.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02.09.2005	01.06.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Piret-Viprey, E Telephone No. +31 70 340-1039

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NL2005/000161

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-21	as originally filed

Claims, Numbers

1-17, 19, 20	received on 02.09.2005 with letter of 02.09.2005
18	received on 19.04.2006 with letter of 19.04.2006

Drawings, Sheets

1/1	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	16,17
	No:	Claims	1-15,18-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D1-D3) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-A-5 897 896
D2: US-A-4 797 288
D3: US-A-4 106 991

The document D4 was not cited in the international search report. A copy of the document is appended hereto.

D4: US 2002/094367 A

1 - The amendment with the letter dated 19.04.2006 was done according to Article 19(2)/Article 34(2)(b) PCT.

New claim 18: original claim 19 + original claim 3 + description (p. 15, l.28).

2 - The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7,9-15,18,20 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D3 is regarded as being the closest prior art.

D3 describes (in col.1, l. 6-17, col.2, l. 27-46, col.2, l. 63 - col.3, l.8, col.3, l.41-50, col.6, l.6-36, ex. XVI and claims 1-3,9-11) the formation of enzymes granulates by:
.mixing a dry powder composition (enzyme powder, filler, 2-40% cellulose fibres maximum length of 150 microns, 0-10% binder),
. wetting of the powder mixture with 5-70% granulating agent (e.g. waxy substance and/or

water),
. processing of the wet powder mixture with the granulating apparatus until the granulate has the desired particle distribution and degree of roundness,
. drying the granulate,
. coating with a melted waxy substance (melting point between 30 and 100°C).
Col.5, l.36-39 indicates a diameter of the dry granules between 0.3-1.5 mm.

- The indication in claim 1 that the granules are "suitable for use in foodstuffs" is not a distinguishing feature between the subject-matter of this claim and the prior art (D3).

Although **some** of the enzyme-containing granules described in the examples of D3 contain ingredients that are not food-grade, D3 concerns (as the present invention) the improvement in or relating to a process for the production of an enzyme granulate and the enzyme granulate thus produced.
The passage col.3, l.19-26 of D3 indicates that all enzymes can be granulated, but preferably amylases and proteinases, such as ALCALASE, ESPERASE, SAVINASE and THERMAMYL. These enzymes are not only used in detergents, as the applicant indicates in his letter of 19-04-2006, but also in dough composition (see D4, par. 65 and 66).
It would thus be obvious for the person skilled in the art, when the improvement of a process for the production of enzyme containing granules "suitable for use in foodstuffs" and the granules thus produced is concerned, to consider D3.

- The subject-matter of claims 1-7,9-15,18,20 differs from D3 in that the agglomerates have an mean diameter in the range of 30-200 microns.

This feature consists in the selection of a diameter range for the granulates.
Such a selection can only be regarded as inventive, if this range presents unexpected effects. However, no such effects are indicated in the application.
On the contrary, the description on p.4, l.30-31, p.6, l.2, p.6, l.18, and the claim 16 indicate a possible broader range: 20-2000 microns. The examples of the description give diameters of the granulates in this broader range; example 1: 500 microns, example 3: 1500 microns.
Furthermore, the diameter of the granules (object of the present invention) obtained in D3 is in the range indicated in claim 1.

Hence, no inventive step is present in the subject-matter of claims 1-7,9-15,18,20.

3 - Dependent claims 8 and 19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:

- in claim 8 a slight constructional change in the composition of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art,

- in claim 19 a slight constructional change in the method of claim 18 is defined which comes within the scope of the customary practice followed by persons skilled in the art.

Consequently, the subject-matter of claims 8 and 19 also lacks an inventive step.

4 - The subject-matter of claims 16,17 is not described, nor suggested in the available prior art (D1-D3).

5 - Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D3 is not mentioned in the description, nor are these documents identified therein.

CLAIMS

1. A composition comprising at least 0.1 wt.% of granules suitable for use in foodstuffs, said granules having an average diameter in the range of 30-3000 μm and comprising:
   a. 3-70 wt.% of a plurality of non-lipophilic particles with an average diameter in the range of 3-300 μm, said particles containing at least 10 wt.% of one or more food components selected from the group of carbohydrates, proteins, salt and functional food ingredients and at least 0.1 wt.% of one or more functional food ingredients, said functional food ingredients being selected from the group of enzymes, oxidoreductants, acidulants, hydrocolloids, micro-organisms, flavours and combinations thereof;
   b. 10-80 wt.% of a discrete continuous phase containing at least 90 wt.% lipids, which continuous phase envelops the non-lipophilic particles and holds them together, the combination of non-lipophilic particles and the continuous phase forming an agglomerate with a mean diameter in the range of 30-200~~20-2000~~ μm; and
   c. 10-80 wt.% of an exterior lipophilic layer that encompasses the agglomerate, which lipophilic layer exhibits a slip melting point of at least 30°C.

2. The composition according to claim 1, wherein the average diameter of the granules is in the range of 40-290 μm, preferably in the range of 50-250 μm, said granules comprising:
   50-90 wt.% of the agglomerate, said agglomerate having a mean diameter in the range of 30-200 μm and containing:
   i. 10-70 wt.% of a plurality of the non-lipophilic particles, said non-lipophilic particles having an average diameter in the range of 10-150 μm, preferably of 20-100 μm; and
   ii. 30-90 wt.% of the discrete continuous phase, said discrete continuous phase exhibiting a slip melting point of at least 30°C; and

10-50 wt.% of the exterior lipid layer, wherein the slip melting point of said exterior lipid layer does not exceed the slip melting point of the discrete continuous phase by more than 5°C.

~~3.The composition according to claim 1, wherein the non-lipophilic particles contain at least 10 wt.% of one or more food components selected from the group of carbohydrates, proteins, salt and functional food ingredients, said functional food ingredients representing at least 0.1 wt.% of the non-lipophilic particles and being selected from the group of enzymes, oxidoreductants, acidulants, hydrocolloids, micro-organisms, flavours and combinations thereof.~~

4.3. The composition according to any one of the preceding claims, wherein the the plurality of non-lipophilic particles represent between 10 and 40 wt.%, preferably between 12 and 35 wt.% of the granules.

5.4. The composition according to any one of the preceding claims, wherein the non-lipophilic particles contain between 0.01 and 5 wt.%, preferably between 0.1 and 3 wt.% of enzyme.

6.5. The composition according to any one of the preceding claims, wherein the non-lipophilic particles contain at least 30 wt.%, preferably at least 50 wt.% of hydrocolloid, flour, gluten, salt, sugar or a mixture thereof.

7.6. The composition according to any one of the preceding claims, wherein the agglomerate contains 25-60 wt.% of the plurality of non-lipophilic particles and 75-40 wt.% of the discrete continuous phase.

8.7. The composition according to any one of the preceding claims, wherein the granules contain 15-30 wt.% of the exterior lipid layer.

9.8. The composition according to any one of the preceding claims, wherein the exterior lipid layer has a thickness in the range of 6-25 μm, preferably of 7-20 μm.

~~10.~~9. The composition according to any one of the preceding claims, wherein the exterior lipid layer exhibits a melting point of 30-50°C, preferably of 32-45°C.

~~11.~~10. The composition according to any one of the preceding claims, wherein the lipids in the discrete continuous phase are selected from the group consisting of triglycerides, diglycerides, monoglycerides, phospholipids, datems, lactems, citrems, acetems, stearyl-lactylates, polyglycerol esters, sucrose esters of fatty acids, fatty acids, waxes, soaps and combinations thereof.

~~12.~~11. The composition according to any one of the preceding claims, wherein the functional food ingredient is selected from the group consisting of enzymes, oxidoreductants, acidulants, micro-organisms, flavours and combinations thereof.

~~13.~~12. The composition according to any one of the preceding claims, wherein the exterior lipophilic layer contains at least 80 wt.% lipids selected from the group consisting of triglycerides, diglycerides, monoglycerides, phospholipids, datems, lactems, citrems, acetems, stearyl-lactylates, polyglycerol esters, sucrose esters, fatty acids, waxes, soaps and combinations thereof.

~~14.~~13. The composition according to any one of the preceding claims, said granules containing:

10-60 wt.% of the plurality of non-lipophilic particles;

15-40 wt.% of the discrete continuous phase; and

15-60 wt.% of the exterior lipophilic layer.

~~15.~~14. The composition according to any one of the preceding claims, wherein the melting point of the exterior layer does not exceed the melting point of the discrete continuous phase.

~~16.~~15. The composition according to any one of the preceding claims, wherein the composition contains at least 1 wt.%, preferably at least 10 wt.%, more preferably at least 90 wt.% of the granules.

3. Use of a granules containing composition ~~according to any one of the preceding claims~~ in the preparation of a dough or a batter, preferably a bread dough, said composition comprising at least 0.1 wt.% of granules suitable for use in foodstuffs, said granules having an average diameter in the range of 30-3000 μm and comprising:

a. 3-70 wt.% of a plurality of non-lipophilic particles with an average diameter in the range of 3-300 μm, said particles containing at least 0.1 wt.% of one or more functional food ingredients

b. 10-80 wt.% of a discrete continuous phase containing at least 90 wt.% lipids, which continuous phase envelops the non-lipophilic particles and holds them together, the combination of non-lipophilic particles and the continuous phase forming an agglomerate with a diameter in the range of 20-2000 μm; and

c. 10-80 wt.% of an exterior lipophilic layer that encompasses the agglomerate, which lipophilic layer exhibits a slip melting point of at least 30°C.

~~18.~~17. A dough or a batter comprising between 0.01 and 5 wt.% of the granules as defined in claim 16.

~~19.~~18. A method of manufacturing a composition according to any one of claims 2-168, said method comprising:

a. providing non-lipophilic particles with an average diameter in the range of 10-150 μm, said particles containing at least 10 wt.% of one or more food components selected from the group of carbohydrates, proteins, salt and functional food ingredients and at least 0.1 wt.% of one or more functional food ingredients, said functional food ingredients being selected from the group of enzymes, oxidoreductants, acidulants, hydrocolloids, micro-organisms, flavours and combinations thereof;

b. combining said non-lipophilic particles with a first molten lipid material with a melting of 30-45°C in a weight ratio of 1:9 to 7:3, followed by mixing so as to obtain a homogeneous dispersion of the non-lipophilic particles in the molten lipid material,

c. converting the homogenous dispersion into agglomerates in which a plurality of the non-lipophilic particles is enveloped by a discrete continuous lipid phase, said agglomerates exhibiting an average diameter in the range of 20-200 μm;

d. coating said agglomerates with a second molten lipid material with a melting point of at least 30°C so as to produce coated agglomerates that are fully encompassed by an exterior lipid layer, wherein the melting point of said exterior lipophilic layer does not exceed the melting point of the discrete continuous lipid phase by more than 5°C;

e. cooling the coated agglomerates to ambient temperature or lower; and

f. collecting the coated agglomerates to obtain the granulate.

~~20.~~19. The method according to claim 1~~8~~9, wherein the homogeneous dispersion is converted into agglomerates by means of spray chilling or extrusion, preferably by spray chilling.

~~21.~~20. The method according to claim 1~~8~~9 or 19~~20~~, wherein the coating step d. employs fluidised bed coating or rotating drum coating.

a. 3-70 wt.% of a plurality of non-lipophilic particles with an average diameter in the range of 3-300 μm, said particles containing at least 0.1 wt.% of one or more functional food ingredients
b. 10-80 wt.% of a discrete continuous phase containing at least 90 wt.% lipids, which continuous phase envelops the non-lipophilic particles and holds them together, the combination of non-lipophilic particles and the continuous phase forming an agglomerate with a diameter in the range of 20-2000 μm; and
c. 10-80 wt.% of an exterior lipophilic layer that encompasses the agglomerate, which lipophilic layer exhibits a slip melting point of at least 30°C.

17. A dough or a batter comprising between 0.01 and 5 wt.% of the granules as defined in claim 16.

18. A method of manufacturing a composition according to any one of claims 2-16, said method comprising:
a. providing non-lipophilic particles with an average diameter in the range of 10-150 μm, said particles containing at least 10 wt.% of one or more food components selected from the group of carbohydrates, proteins, salt and functional food ingredients and at least 0.1 wt.% of one or more functional food ingredients, said functional food ingredients being selected from the group of enzymes, oxidoreductants, acidulants, hydrocolloids, micro-organisms, flavours and combinations thereof;
b. combining said non-lipophilic particles with a first molten lipid material with a melting of 30-45°C in a weight ratio of 1:9 to 7:3, followed by mixing so as to obtain a homogeneous dispersion of the non-lipophilic particles in the molten lipid material,
c. converting the homogenous dispersion into agglomerates in which a plurality of the non-lipophilic particles is enveloped by a discrete continuous lipid phase, said agglomerates exhibiting an average diameter in the range of ~~2~~30-200 μm;
d. coating said agglomerates with a second molten lipid material with a melting point of at least 30°C so as to produce coated agglomerates that

are fully encompassed by an exterior lipid layer, wherein the melting point of said exterior lipophilic layer does not exceed the melting point of the discrete continuous lipid phase by more than 5°C;

e. cooling the coated agglomerates to ambient temperature or lower; and

f. collecting the coated agglomerates to obtain the granulate.

19. The method according to claim 18, wherein the homogeneous dispersion is converted into agglomerates by means of spray chilling or extrusion, preferably by spray chilling.

20. The method according to claim 18 or 19, wherein the coating step d. employs fluidised bed coating or rotating drum coating.